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DATE: October 9, 2007

Application No: 09/055,744 **Our Ref:** 1038-746 MIS:jb

TO:	FAX #	PHONE #
US Patent and Trademarks Office **Mail Stop Appeal Brief-Patents**	(571) 273-8300	

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FROM: Michael I. Stewart / 416-849-8400

COMMENTS:

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	36

Application Number	09/055,744
Filing Date	April 7, 1998
First Named Inventor	Charles D.Y. Sia
Art Unit	1648
Examiner Name	Emily M. Le
Attorney Docket Number	1038-746 MIS:jb

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
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- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Sim & McBurney		
Signature			
Printed name	Michael I. Stewart		
Date	October 9, 2007	Reg. No.	24,973

CERTIFICATE OF TRANSMISSION/MAILING

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Typed or printed name	Michael I. Stewart	Date	October 9, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Charles D.Y. Sia, et al.	Confirmation No.: 4350
Appl'n. No.	:	09/055,744	
Filed	:	April 7, 1998	
Title	:	HIV-SPECIFIC CYTOTOXIC T-CELL RESPONSES	
Grp./A.U.	:	1648	
Examiner	:	Emily M. Le	
Docket No.	:	1038-746 MIS:jb	
Date	:	October 9, 2007	

RESPONSE

BY FACSIMILE **(571) 273-8300**

Mail Stop Appeal Brief-Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
U.S.A.

Dear Sir:

In response to Notification of Non-Compliant Appeal Brief dated September 13, 2007, submitted herewith is an Amended Appeal Brief in triplicate. Other than to mention the Notification in the Introduction paragraph, the Amended Appeal Brief is unchanged except for the deletion of the heading "Summary" on page 7.

The notification indicated that the Appeal Brief was defective on the basis that:

> "The brief do not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order".

It is submitted that such is not the case. 37 CFR 41.37(c) requires that:

> "The brief shall contain the following items under appropriate headings and in the order indicates in paragraphs (c)(1)(i) through (c)(1)(x) of this section..."

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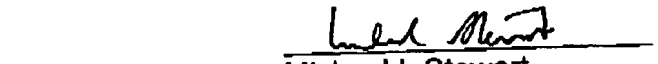
In the explanation contained in the Notification, it is stated:

> "In this case, the brief does not contain the items required under 37 CFR 41.37(c) in the proper order. For example, instead of having the claims appendix after the arguments section, the instant brief contains a summary section in between the two sections." (emphasis added)

The heading "10. Summary" has been deleted. It is submitted that the c(1)(i) and c(1)(x) of 37 CFR 41.37 appear in the Amended Appeal Brief in the order required by the Rule. The fact that applicant precedes those items with two additional items, namely an Introduction and Extension of Time, does not alter the fact the Amended Appeal Brief contains each of the items specified in 37 CFR 41.37(c)(1)(i) to 37 CFR 41.37(c)(1)(x). The Rule does not preclude the addition of further paragraphs, so long as the Appeal Brief includes those specified in the rule under the stated headings.

It is submitted that the Amended Appeal Brief complies with 37 CFR 1.37(c)(1).

Respectfully submitted,



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Examiner	:	Emily M. Le	
Docket No.	:	1038-746 MIS:jb	
Date	:	October 9, 2007	

AMENDED APPEAL BRIEF

BY FACSIMILE **(571) 273-8300**

Mail Stop Appeal Brief-Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
U.S.A.

Dear Sir:

1. Introduction

This amended Appeal Brief is being submitted in triplicate in response to applicants appeal from the Final Rejection of claims 1 and 4 to 11 and in response to the Notifications of Non-compliant Appeal Brief dated December 29, 2005 and September 13, 2007. Authorization to charge the prescribed fee to our deposit account is attached. Three copies of this Appeal Brief are submitted herewith.

2. Extension of Time

Petition was made in the Appeal Brief submitted October 11, 2005 under provisions of 37 CFR 1.136(a) for an extension of one month of the period for submitting the Appeal Brief. Authorization to charge the prescribed fee to our deposit account was enclosed with that Appeal Brief.

3. Real Party of Interest

The real party of interest in this application is Sanofi Pasteur Limited. An Assignment from the inventors to Connaught Laboratories Limited was recorded October 8, 1998 under Reel/Frame 9333/0988. Since that date, Connaught Laboratories Limited has undergone two changes of names, first to Aventis Pasteur Limited and subsequently to Sanofi Pasteur Limited. Documentation recording these changes of name with respect to this application has been forwarded to the PTO for recordal and have now been recorded as Reel/Frame 017070/0469 in respect of the first change of name. The recordal particulars for the second change of name have not yet been received.

4. Related Appeals and Interferences

There are no other appeals and interferences known to the appellant, the appellant's legal representative or assignee which may be related to directly affect or be directly affected by or having a bearing on the Board's decision in this pending appeal. However, applicants draw attention to pending application No. 09/647,981.

5. Status of Claims

This application was filed with 15 claims. Claims 12 to 15 are allowed. Claims 2 and 3 have been cancelled. Claims 1, 4, 6, 7, 10 and 11 have been amended. Claims 5, 8, 9 and 11 are unamended. Claims 1 and 4 to 11 are appealed. The claims appealed are listed in a claims Appendix hereto.

6. Status of Amendments

There have been two amendments filed subsequent to Final Action, the first filed June 8, 2005 and the second simultaneously herewith. According to an Advisory Action dated June 28, 2005, the first Amendment was entered. An Advisory

Action on the second Amendment dated March 24, 2006 indicated that the Amendment entered.

7. Summary of Claimed Subject Matter

The present invention is concerned, as defined in claim 1, with a method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host (page 2, lines 26 to 29). The method comprises the steps of administering to the host a T-helper molecule to prime T-helper cells of the immune system of the host and subsequently administering to the host a mixture of the T-helper molecule and T-cell inducing HIV-derived molecule to generate an HIV-specific T-cell response in the host (page 2, line 30 to page 3, line 2). Claim 1 is also limited to the generation of the T-cell response in a host possessing MHC class I HLA A2 molecules (page 6, line 33 to page 8, line 16).

The T-helper molecule may be the peptide CLP-243 (SEQ ID No: 10) (claim 4; page 3, lines 12 to 16), which may be administered with an adjuvant (claim 5; page 3, lines 16 to 17).

The T-cell inducing HIV molecule may include a peptide having an amino acid sequence which is that of a portion of an HIV-1 antigen and which contains a T-cell epitope (claim 6; page 3, lines 18 to 20), which may be a portion of the Rev protein of HIV-1 (claim 7; page 3, lines 21 to 22).

The peptide may be a lipopeptide (claim 8; page 3, line 30), particularly where the lipid is palamtoyl or cholesterol (claim 9; page 3, lines 32 to 33).

The method is particularly carried out using CLP-243 as the T-helper molecule and CLP-175 or CLP-176 as the lipopeptide (claim 10; page 3, lines 12 to 16, page 3, line 33 to page 4, line 2).

The mixture of the T-helper molecule and the T-cell inducing HIV-derived molecule may be administered with a suitable adjuvant (claim 11; page 4, lines 3 to 5).

8. Grounds of Rejection to be Reviewed on Appeal

In the Final Action, the Examiner presented two grounds of rejection:

(a) Claims 1 and 4 to 11 remain rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The Examiner considered that the claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This issue is under consideration on this appeal.

(b) Claims 1 and 4 to 11 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 to 11 of copending Application No. 09/647,981. The rejection is a provisional one, since the conflicting claims have not been patented. Since the rejection is a provisional one, it is not the subject of this appeal.

9. Argument

(a) The invention

The present invention is based on experimental findings by the inventors:

(1) that two nanomer peptides, CLP-177 and CLP-72, a hexamer designated CLP-178 and a 12-mer designated CLP-182 of the HIV-1 (LAI) REV protein were individually able to bind and stabilize membrane-bound the HLA class I molecule HLA-2; and

(2) that a long peptide (SEQ ID No: 9), encompassing the amino acid residues 52 to 116 of HIV-1 (LAI) Rev proteins and constructed by having a single cholesterol or palamtoyl moietly attached to its amino terminus via a KSS linker to form lipopeptides, CLP-175 and CLP-176 respectively, is capable of eliciting CTL as well as antibody responses in HLA-A2 transgenic mice.

Having regard to these experimental results, applicants have provided a sound immunization protocol for inducing a HIV-specific cytotoxic T-cell response in a host by initial administration of a T-helper molecule to prime the immune system of the host followed by administration of a mixture of the T-helper molecule and a peptide having an amino acid sequence which is that of a portion of an HIV antigen which contains a T-cell epitope.

In considering the Examiner's rejection of lack of enablement, it is important to consider what is claimed in independent claims 1 and 10. What is claimed is a method of generating an HIV-specific cytotoxic T-cell response in the host.

(b) Rejection of claims 1 and 4 to 11 under 35 USC 112, first paragraph

The Examiner considered that the enablement requirement with respect to claims 1 and 4 to 11 has not been met. At the heart of the Examiner rejection is the statement contained in the Office Action of May 27, 2004 that:

> "... the nature of the invention is directed to a method that comprises a prime and boost protocol that uses T-helper molecules and T-cell inducing HIV-molecules to generate an HIV-specific cytotoxic (CTL) response in a host. While it is acknowledged... that applicant does 'not promise that the procedure of the invention is a vaccination procedure against HIV and neither does applicants data demonstrate the same'; however, this does not evade the obvious fact that the instantly claimed invention reads on a vaccine method that is used to treat and/or prevent HIV infection through the generation of HIV-specific cytotoxic T-cell response in the host."

In considering compliance of the claims with the provision of 35 USC 112, first paragraph, it is submitted that consideration of what actually is claimed is required. What is claimed in the present application is a method of generating HIV-specific cytotoxic T-cell responses in a host and NOT a vaccine method that is used to treat and/or prevent HIV infection, as asserted by the Examiner in the above quotation.

The Examiner states in the Final Action that:

> "The issue at hand is that the claimed method, in view of the specification, reads on a method of treating or preventing HIV infection. While this is not explicitly recited in the claims, however, claimed matter is interpreted in view of the disclosure." (emphasis added)

The Examiner goes on to say in the Final Action that:

> "In the instant [application], the claims recite a method of generating an HIV-specific cytotoxic T-cell response in a host."

This is quite correct, as discussed above, but the Examiner adds another comment:

> "However, what biological activity can be ascertained by the generation of an HIV-specific cytotoxic T-cell response in a host? .... The biological activity that can be ascertained by the implementation of the claimed method is not readily apparent in the claims."

It is submitted that applicants claims do not need to recite a biological activity. It is sufficient for applicants claims that a CTL response is generated in a host and that the recited method steps are used to effect that generation. Nevertheless, the Examiner imposes an additional requirement on applicants language.

The Examiner then turns to the specification and discusses several passages from the disclosure and then concludes, in the Final Action, that:

> "Ergo, in view of the disclosure provided by the applicants, the Examiner concludes that the intended purpose of the claimed invention

> is directed to a protocol for the treatment for and/or prevention of HIV." (emphasis added)

It is submitted that it is improper for the Examiner to interpret applicants claims in this way. Applicants disclosure, while discussing HIV neither describes nor promises a method for the treatment and/or the prevention of HIV. All that applicants promise and demonstrate is a method of generating an HIV-specific CTL response in a host and that is what is claimed.

It is agreed with the Examiner that, as stated in the May 27, 2004 Office Action, that:

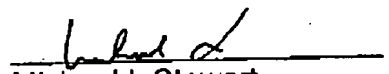
> ".....it is well known in the art that retroviral infections in general, and HIV infections in particular, are refractory to anti-viral therapies. The obstacles to HIV/AIDS therapy and vaccine formulations are well documented in the literature."

It is for that reason that applicants do not promise to have provided such a therapy.

For these reasons, it is believed that the Examiner is in error in rejecting claims 1 and 4 to 11 under 35 USC 112, first paragraph, for lack of enablement.

Having regard to the above, it is submitted that the rejection of claims 1 and 4 to 11 under 35 USC 112, first paragraph, should be reversed.

Respectfully submitted,



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CLAIMS APPENDIX

1. A method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host possessing MHC class I HLA A2 molecules, which comprises:

administering to the host a T-helper molecule to prime T-helper cells of the immune system of the host, and

subsequently administering to the host a mixture of said T-helper molecule and a T-cell inducing HIV molecule which bind to MHC class I HLA A2 molecules to generate an HIV-specific cytotoxic T-cell (CTL) response in the host.

4. The method of claim 1 wherein said T-helper molecule is CLP-243 (SEQ ID No: 10).

5. The method of claim 1 wherein said T-helper molecule is administered with an adjuvant.

6. The method of claim 1 wherein said T-cell inducing HIV molecule includes a peptide having an amino acid sequence which is that of a portion of an HIV-1 antigen, said peptide containing at least one T-cell epitope.

7. The method of claim 6 wherein said peptide having an amino acid sequence which is that of a portion of the Rev protein of HIV-1.

8. The method of claim 6 wherein said peptide is a lipopeptide.

9. The method of claim 8 wherein the lipid is palmitoyl or cholesterol.

10. A method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host possessing MHC class I HLA A2 molecules, which comprises:

administering to the host a T-helper molecule which is CLP-243 (SEQ ID No: 10) to prime T-helper cells of the immune system of the host, and

subsequently administering to the host a mixture of said T-helper molecule and a T-cell inducing HIV molecule capable of binding to MHC class I HLA A2

molecule, said T-cell inducing HIV molecule being CLP-175 or CLP-176 to generate an HIV-specific cytotoxic T-cell (CTL) response in the host.

11. The method of claim 6 wherein said mixture is administered with an adjuvant.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.